IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, *et al.*, *Defendants*.	No. 1:19-cv-00272-LCB-LPA

MEMORANDUM IN SUPPORT OF STATE HEALTH PLAN DEFENDANTS' MOTION IN LIMINE TO EXCLUDE EXPERT TESTIMONY BY REBUTTAL EXPERT WITNESSES RANDI ETTNER, PH.D., DAN KARASIC, M.D., AND JOHANNA OLSON-KENNEDY, M.D.

I. Introduction

Plaintiffs identified three rebuttal expert witnesses: Randi Ettner, Ph.D., Dan Karasic, M.D., and Johanna Olson-Kennedy, M.D. The Court should limit the testimony of these three experts for two reasons. First, the Court should enforce the limitations set by the discovery process. All three witnesses were disclosed as rebuttal experts; their role is to rebut the opinions of the Plan's expert witnesses. Rebuttal experts "cannot put forth their own theories; they must restrict their testimony to attacking the theories offered by the adversary's experts." *Boles v. United States*, No. 1:13-cv-489, 2015 WL 1508857, at *2 (M.D.N.C. Apr. 1, 2015) (Auld, J.) (*IBM v. Fasco Indus.*, No. C–93–20326 RPA, 1995 WL 115421, at *3 (N.D.Cal. Mar. 15, 1995)). To the extent these witnesses provide independent theories and opinions about gender

dysphoria, such testimony is beyond the scope of the role of a rebuttal expert. This Court should prevent them from introducing this evidence.

Second, the expert opinions from the rebuttal expert witnesses reflect unreliable scientific opinion. Under Rule 702, this Court has "a special gatekeeping obligation" to "ensure that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021) (emphasis in original).

The proposed testimony from Drs. Ettner, Karasic, and Olson-Kennedy is not reliable evidence for the medical necessity of the hormone and surgical treatments Plaintiffs seek. Under *Daubert*, this Court must evaluate "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592–93 (1993).

Experts are to present opinions "based on scientific, technical, or other specialized knowledge and not on belief or speculation, and [any] inferences must be derived using scientific or other valid methods." *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (emphasis in original). In its "ideal

expression," science examines the world "in a rigorous, disciplined manner in, whenever possible, controlled environments" and does so "based on principles of hypothesis generation, scrupulous study design, meticulous data collection, and objective interpretation of experimental results." Jerome P. Kassirer & Gladys Kessler, "Preface", National Research Council, *Reference Manual on Scientific Evidence* xiii (3d ed. 2011).

Plaintiffs' experts fail to do so. The citations in the rebuttal opinions reflect the core difficulty with the evidence Plaintiffs rely upon for their claims: the latest scientific evidence does not support the medical necessity of hormone treatment or surgery for treatment of gender dysphoria. Such treatments remain experimental.[1] Accordingly, this Court should preclude Drs. Ettner,

[1] To be clear: Plan Defendants do not *prevent* Plaintiffs or any other Plan beneficiary from receiving these experimental treatments. The issue before this Court is whether the Plan *must pay for* hormonal and surgical treatments for gender dysphoria, despite the Plan's view that the treatments are experimental and unlikely to alleviate their distress. For mental health counseling, discovery has shown that the Plan does not actually restrict—and since at least 1990 has not restricted—mental health counseling services on the basis of diagnosis. Such benefits are available for treatment of Plaintiffs' gender dysphoria as they would be for other psychiatric illnesses. To the extent the Plan's benefit booklets were incorrect on this point, they have been fixed. *See* Doc. 137 at 13 n.2.

Karasic, and Olson-Kennedy, and Drs. Brown and Schechter in their rebuttal capacity, from offering testimony on this point to the jury.

II. Legal Standard

A. Rebuttal witnesses must offer testimony to contradict or rebut assertions made by the other party's witnesses; they cannot offer rebuttal experts to 'bolster their case in chief.'

This Court ordered Plaintiffs to disclose expert witnesses by March 1, 2021. Doc. 61. This Court ordered Plaintiffs to disclose rebuttal expert witnesses for the Plan experts by June 1, 2021 (an additional ten days were permitted for the rebuttal reports from Drs. Brown and Ettner). Doc. Nos. 98 & 101.

Rebuttal expert witnesses present testimony "intended solely to contradict or rebut evidence on the same subject matter identified by another party" in the initial expert witness disclosures. Fed. R. Civ. P. 26(a)(2)(D)(ii) (emphasis added). Rebuttal testimony is therefore limited. "Ordinarily, rebuttal evidence may be introduced only to counter new facts presented in the defendant's case in chief. Such new facts might include 'surprise' evidence presented by the defendants. Permissible rebuttal evidence also includes evidence unavailable earlier through no fault of the plaintiff." *Allen v. Prince*

George's Cnty., Md., 737 F.2d 1299, 1305 (4th Cir.1984). Plaintiffs' rebuttal experts can testimony "to explain, repel, counteract, or disprove facts given in evidence by the opposing party." *United States v. Stitt,* 250 F.3d 878, 897 (4th Cir. 2001).

What rebuttal experts cannot do is introduce new theories or interpretations on rebuttal. "[E]xpert reports that simply address the same general subject matter as a previously-submitted report, but do not directly contradict or rebut the actual contents of that prior report, do not qualify as proper rebuttal or reply reports." *Boles v. United States*, No. 1:13CV489, 2015 WL 1508857, at *2 (M.D.N.C. Apr. 1, 2015) (quoting *Withrow v. Spears*, 967 F.Supp.2d 982, 1002 (D.Del.2013)).

"In other words, a party may not offer testimony under the guise of 'rebuttal' only to provide additional support for his case in chief." *Funderburk v. S.C. Elec. & Gas Co.*, No. 3:15-CV-04660-JMC, 2019 WL 3406814, at *3 (D.S.C. July 9, 2019) (internal punctuation omitted). "Thus, '[r]ebuttal experts cannot put forth their own theories; they must restrict their testimony to attacking the theories offered by the adversary's experts." *Id.* "[E]xpert reports that simply address the same general subject matter as a previously-submitted

report, but do not directly contradict or rebut the actual contents of that prior report, do not qualify as proper rebuttal or reply reports." *Id.* at *4.

B. Daubert also requires exclusion of testimony that does not have a reliable methodology that this Court has evaluated prior to submission of the information to the jury.

This Court's "gatekeeping role," *Daubert*, 509 U.S. at 597, is "to exclude speculative or unreliable testimony to ensure accurate, unbiased decision-making by the trier of fact," *Lovett v. Omni Hotels Mgmt. Corp.*, 2016 WL 777781 at *4 (N.D. Cal. Feb. 29, 2016) (Seeborg, J.). *Daubert* "applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). Testimony by a qualified expert must (1) "help the trier of fact to understand the evidence or to determine a fact in issue," (2) be "based upon sufficient facts or data," (3) be "the product of reliable principles and methods," and (4) "reliably appl[y] the principles and methods to the facts of the case." *Lovett*, 2016 WL 777781 at *4.

This Court must ensure that an expert's opinion is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999) (emphasis in

original). To the extent an expert makes inferences based on the facts presented to him, this court must ensure that those inferences were "derived using scientific or other valid methods." *Sardis*, 10 F.4th at 281

In assessing reliability, the four "non-exhaustive guideposts" of *Daubert*'s analysis are: (1) whether the expert's theory or technique "can be (and has been) tested," (2) "whether the theory or technique has been subjected to peer review and publication," (3) "the known or potential rate of error" inherent in the expert's theory or technique, and (4) whether the expert's methodology is generally accepted in his field of expertise. *Nease*, 848 F.3d at 229 (quoting *Daubert*, 509 U.S. at 593–94). While the Court has "broad latitude" to apply "reasonable measures of reliability in a particular case," its focus must be on "the principles and methodology" the expert used to develop the challenged testimony. *Sardis*, 10 F.4th at 281.

These four *Daubert* guideposts "neither necessarily nor exclusively appl[y] to all experts or in every case;" the relevance of some factors can "depend on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *Sardis*, 10 F.4th at 281 (quoting *Kumho* 526 U.S. at 141). "When addressing an expert whose methodology is grounded in

experience," the court analyzes "three factors: (1) how the expert's experience leads to the conclusion reached; (2) why that experience is a sufficient basis for the opinion; and (3) how that experience is reliably applied to the facts of the case." This Court has therefore applied a different set of factors for expert witnesses who testify based upon their experience, rather than science. "[W]here an expert relies on his experience and training and not a particular methodology to reach his conclusions, application of the *Daubert* analysis is unwarranted." *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F.Supp. 3d 529, 537 (M.D.N.C. 2019) (Biggs, J.); *see also U.S. v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007) (While methodology for experiential witness is "somewhat more opaque, the district court must nonetheless require" the witness to explain how their testimony meets these three factors.).

As discussed below, however, Plaintiffs' rebuttal witnesses must still present evidence that is the result of a *reliable* and verifiable methodology in support of their claims for the medical necessity of hormone treatment and surgery for treatment of gender dysphoria. They do not. Their evidence is dated and of low quality. Recent scientific reviews have concluded that these studies are of low quality and should not be relied upon to determine the care for

transgender individuals. Accordingly, this Court should exercise its gatekeeping role and exclude testimony from Drs. Ettner, Karasic, and Olson-Kennedy, and rebuttal testimony about the medical necessity of hormone and surgical treatments for gender dysphoria on this basis as well.

III. Dr. Ettner, Dr. Karasic, and Dr. Olson-Kennedy provide extensive opinions in rebuttal that are inappropriate for a rebuttal expert. This Court should exclude them.

As noted above, rebuttal experts cannot put forth their own theories. They must restrict their testimony to attacking the theories offered by the Plan's experts. Courts in this circuit do not allow rebuttal experts who "simply address the same general subject matter as a previously-submitted report, but do not directly contradict or rebut the actual contents of that prior report." *Funderburk*, 2019 WL 3406814, at *4. Significant portions of the rebuttal reports from Drs. Ettner, Karasic, and Olson-Kennedy are inadmissible on this basis and should be excluded.

Dr. Ettner explicitly state that the initial portion of her expert report provides "necessary context in the form of an overview" of the medical issues involved with treatment of gender dysphoria. Ettner Rebuttal Rep. ¶20. Such opinions are not rebuttal testimony. They are additional support for Plaintiffs'

case in chief. The Court should therefore exclude the (largely uncited) opinions presented by Dr. Ettner that are not connected to her criticism of the opinions of the Plan Defendants' experts. These opinions are expressed at paragraphs 20 through 62 and concluding paragraph 106 of the Ettner Rebuttal report. Ettner Rebuttal Rep. ¶¶ 20-62 & 106.

Dr. Karasic's rebuttal report has the same structure and the same error. Dr. Karasic's broad statements about gender dysphoria are only appropriate for an affirmative witness disclosed in accordance with this Court's case management orders. This Court should preclude any consideration of the opinions presented in paragraphs 19 to 42 of Dr. Karasic's report. Karasic Rebuttal Rep. ¶¶19-42.

Dr. Olson-Kennedy's report similarly exceeds its evidentiary purpose. As a rebuttal witness, she cannot present "necessary background information" about the diagnosis and treatment of gender dysphoria. Olson-Kennedy Rebuttal Rep. at 5 n.1. The Court should therefore exclude all opinions expressed by Dr. Olson-Kennedy at paragraphs 18 to 49 and in her conclusion paragraphs 110 & 111. Olson-Kennedy Rebuttal Rep. ¶¶ 18-49, 110-111.

IV. The studies identified by Plaintiffs' rebuttal experts do not provide reliable, valid evidence to support a conclusion that hormonal or surgical treatment improves the mental health of individuals with gender dysphoria.

The most recent definition of "Gender Dysphoria" is from the FIFTH EDITION OF THE DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (2013) ("***DSM-V***"). (PLANDEF0202999-0203007). As a "general descriptive term," gender dysphoria "refers to an individual's affective/cognitive discontent with the assigned gender but is more specifically defined when used as a diagnostic category" under the DSM-V. *Id.* (PLANDEF0202999) (emphasis added). The DSM-V diagnosis of gender dysphoria "refers to the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender." *Id.* (emphasis added).

Dissatisfaction with one's gender by itself is not a mental health issue, so treatment for such dissatisfaction by itself is not "treatment, cure, or relief of a health condition, illness, injury, or disease" (*i.e.* medically necessary). The treatment must be directed at the distress that interferes with the daily activities of life.

In the United Kingdom, the National Health Service commissioned an an independent review of the medical science supporting the use of hormone

therapy to treat gender dysphoria. To support this effort, that country's National Institute for Health and Care Excellence (NICE) reviewed the existing scientific evidence. *See* Evidence Review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria (2020) (PLANDEF0204216-0204346) (NICE GnRH Study); Evidence Review: Gender-affirming hormones for children and adolescents with gender dysphoria (2020) (PLANDEF0202803-0202958) (NICE Hormone study).

These reviews both found that the "key limitation" in the existing medical literature was "the lack of reliable comparative studies." NICE GnRH Study at 12 (PLANDEF0204227); NICE Hormone Study at 13 (PLANDEF0202815). Put in the most basic terms: there are no studies in which physicians provide a medical intervention to one group of patients, while withholding that same intervention to other patients. These controlled trials allow scientists to determine whether the proposed treatment has a positive income. Instead, the studies are "small, uncontrolled observational studies." NICE GnRH Study at 13 (PLANDEF0203228); NICE Hormone Study at 13 (PLANDEF0202815). In these studies, the hormone therapy is provided to a patient, and there is follow-up to determine whether the patient has improved.

For a psychiatric illness, such as gender dysphoria, the follow-up is usually a patient survey or interview.

The NICE review for puberty blocking treatment (used at the onset of pubertal changes to stop further maturation of the body) found that the study conclusions were of "very low certainty" using the standard scientific method that medical researchers use to evaluate clinical studies. NICE GnRH Study at 13. (PLANDEF0204228). The studies "suggest very little change" in the "critical outcomes of gender dysphoria and mental health (depression, anger and anxiety)" and the "important outcomes of body image and psychosocial impact" in children and adolescents who undergo this treatment. *Id.*

As part of the pubertal process, bone density increases for adolescents. Puberty blocking treatments, therefore, cannot continue indefinitely. The patient must decide whether to allow the body's biological puberty process to resume or to transition to cross-sex hormone treatment. The NICE review for hormone therapy found similar limitations in the study methodologies. These "uncontrolled observational studies" are subject to are "of very low certainty" using an accepted approach to evaluate the strength of medical evidence. NICE Hormone Study at 13 (PLANDEF0202815). In other words, all improvement

reported by the studies could be "attributed to a regression-to-the-mean." *Id.* That is, the evidence is statistically insignificant and any improvement could be due to no more than natural variation. The ultimate conclusion of the evidence review is the study "found limited evidence for the effectiveness and safety of gender-affirming hormones in children and adolescents with gender dysphoria, with all studies uncontrolled, observational studies, and all outcomes of very low certainty. *Id.* at 50 (PLANDEF0202852).

As an example of the challenge with the follow-up studies, consider a study performed by one of the rebuttal experts, Dr. Olson-Kennedy. *See* Johanna Olson-Kennedy, *et al.*, Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults: Comparisons of Nonsurgical and Postsurgical Cohorts, JAMA Pediatrics 172(5):431-436 (2018) (PLANDEF0203144-0204149). In this study, researchers surveyed transgender patients at gender-specific clinics. Researchers surveyed patients who had received chest surgery and those who had a diagnosis of gender dysphoria but had not received this surgery. *Id.* The researchers' survey data indicated that "chest reconstruction had a positive both [on] transmasculine minors and young adults." *Id.* at 435 (PLANDEF0204148).

The difficult with this study is two-fold. First, "chest dysphoria" is not a medical term. For purposes of determining whether a procedure is medically necessary, the question is whether the treatment improves the mental distress that arises as a result of the patient's gender dysphoria. Second, as is the case with many of retrospective surveys, a number of patients refuse to participate. For this study, 26% of the postsurgical patients were either unreachable or refused to participate. *Id.* at 433 (PLANDEF0204146).

The rebuttal experts defend the validity of these studies with a similar response: other medical guidelines have "low quality" evidence; patient care can outpace scientific study; it would be unethical to conduct randomized-controlled trials for these treatments for transgender patients. Ettner Rebuttal Rep. ¶ 84; Karasic Rebuttal Rep. ¶ 76; Olson-Kennedy ¶ 95; Schechter Rebuttal Rep. ¶¶ 24-26; Brown Rebuttal Rep. ¶¶50-52.

These arguments are about methodology and whether the conclusion reached thereby are valid. This disagreement should be assessed in the context of a *Daubert* hearing.[2]

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[2] Plaintiffs' rebuttal experts also, at various points in their reports, refer to experience as a treating physician in support of their conclusions. Even if the Court concludes that experiential testimony—rather than the scientific

Medical science is trending strongly away from the conclusion that hormonal and surgical treatment improves the distress suffered by patients suffering from gender dysphoria. As noted in earlier filings to this Court, Finland, Sweden, and the United Kingdom have all retreated from their prior medical policies that made cross-sex hormones and surgical treatments widely available. Medical providers in these countries now restrict the use of hormones and surgery in minors based on identified gaps in the medical science. Doc. 197 at 14-15.

V. Conclusion.

This Court should exclude the non-rebuttal testimony that Plaintiffs' rebuttal experts seek to introduce and must evaluate the methodology of the remaining evidence about the efficacy of treatment for gender dysphoria. When

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testimony that underlies evidence-based medicine—is appropriate, Plaintiffs' experts must still provide sufficient information to permit this Court to assess the methodology underlying their opinions. "Whether expert evidence is reliable is primarily a question of the validity of the expert's methodology, not the quality of the data used or the conclusions produced." *Krakauer v. Dish Network, L.L.C.*, No. 1:14-cv-333, 2015 WL 5227693, at *5 (M.D.N.C. Sept. 8, 2015) (emphasis added). The factfinder must be able to assess "how the expert's experience leads to the conclusion reached." *Mod. Auto. Network*, 416 F.Supp. 3d at 537. *Daubert* does not envision the admission of "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert," *Kumho*, 526 U.S. at 157, as is the case with Plaintiff experts' reference to their experience.

it does so, the Court should find their conclusions unreliable and exclude or limit their rebuttal testimony accordingly.

Respectfully submitted this the 10th day of June, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of June, 2022, the foregoing was filed electronically with the Clerk of Court using the CM/ECF electronic filing system, which will send notification of such filing to all registered users.

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CERTIFICATE OF WORD COUNT

Pursuant to L.R. 7.3(d)(1), the undersigned certifies that the State Health Plan Defendants' Motion in Limine to Exclude Testimony by George Brown, M.D., and Loren Schechter, M.D. complies with the Court's word limit as calculated using the word count feature of the word processing software. Specifically, the Memorandum in Support contains less than 6,250 words, including the body of the Memorandum and headings, butnot including the caption, signature lines, this certificate, or the certificate of service.

This the 10th day of June, 2022.

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